

## REMARKS

### Status of the Claims

Claims 1-9, 12, 22-24, and 55-81 are pending in the application, with claims 1, 55, and 59 being independent. Claims 1, 7, 8, 12, 23, 55, and 59 are amended herein. Additionally, Applicants have added new claims 62-81 to provide an additional scope of protection commensurate with the original disclosure. No new matter has been added.

Unless explicitly stated otherwise, none of the amendments to the claims were made for reasons substantially related to the statutory requirements for patentability. Furthermore, unless stated otherwise, the amendments to the claims were made simply to make express what had been implicit in the claims as originally worded and therefore are not narrowing amendments that would create any type of prosecution history estoppel.

### Priority

In the Non-Final Office Action mailed June 3, 2009, the Examiner alleges that the disclosure of the prior-filed application, U.S. Provisional Patent Application No. 60/255,603 (hereinafter, “the priority application”) fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. § 112 for one or more claims of the application. Specifically, the Examiner alleged that the priority application fails to provide support for the limitation “wherein the second material comprises rigid particles which are dispersed homogenously throughout at least a portion of the first material.”

Applicants respectfully disagree, and submit that sufficient support for this feature can be found, for example, at least at page 16, lines 21-29 of the priority application (reproduced below with emphasis added):

In the third function, the additive remains, typically to serve a structural function (i.e. to lend mechanical strength or rigidity to the microneedles). For example, a dispersion of rigid salt particles in PLGA can enhance the rigidity of PLGA microneedles.

Accordingly, Applicants submit that the priority application contains sufficient support for the feature identified by the Examiner to meet the requirements under 35 U.S.C. § 112. Applicants

respectfully request that the Examiner recognize the filing date of the priority application as the effective filing date of the present application for the currently pending claims.

### **Claim Rejections - 35 U.S.C. § 112**

In the Non-Final Office Action mailed June 3, 2009, the Examiner rejected claim 59 as lacking sufficient antecedent basis for the term “the polymer.” Applicants have amended claim 59 to replace the term “the polymer” with the term “the first material.” Applicants respectfully submit that the amendment to the claim overcomes the rejection and request withdrawal of this rejection.

### **Claim Rejections - 35 U.S.C. § 102(e)**

#### **Arias**

In the Non-Final Office Action mailed June 3, 2009, the Examiner rejected claims 1-6 22-24, 55-57, 59, and 60 under 35 U.S.C. § 102(e) as allegedly being anticipated by Arias et al. (US 2002/0133129, hereinafter “Arias”). Applicants respectfully submit that Arias is an improper reference under 35 U.S.C. § 102(e).

Arias has a filing date of March 13, 2001. An earlier claim of priority was not made in the Arias application. As noted above, the present application is entitled to the filing date of the priority application filed December 14, 2000. The present application has an earlier effective filing date than Arias. Therefore, Arias is an improper reference under 35 U.S.C. § 102(e).

#### **Dalton**

The Examiner also rejected claims 1, 7-9, 12, and 55-61 under 35 U.S.C. § 102(e) as allegedly being anticipated by Dalton et al. (US 2005/0197308, hereinafter “Dalton”). Applicants respectfully submit that Dalton is an improper reference under 35 U.S.C. § 102(e).

Dalton has a filing date of December 20, 2004, and claims priority to U.S. Patent Application No. 10/333,448 filed August 12, 2003. As noted above, the present application has an effective filing date of December 14, 2000. Therefore, the present application has an earlier

effective filing date than Dalton. In addition, the actual filing date of the present application, December 13, 2001, also predates the effective date of Dalton as a reference under 35 U.S.C. § 102(e). Therefore, Dalton is an improper reference under 35 U.S.C. § 102(e).

### **Summary**

For at least the foregoing, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. § 102(e).

### **No Waiver**

All of Applicants' arguments and amendments are without prejudice or disclaimer. Applicants have not addressed each specific rejection of the independent and dependent claims because Applicants submit that the independent claims are allowable over the documents of record, as discussed above. Applicants have not acquiesced to any such rejection and reserve the right to address the patentability of any additional claim features in the future.

### **CONCLUSION**

The foregoing is submitted as a full and complete response to the Non-Final Office Action mailed June 3, 2009, and early and favorable consideration of the claims are requested. If the Examiner believes that any informalities remain in the application that may be corrected by Examiner's amendment, or if any other issues exist that can be resolved by a telephone interview, please call the undersigned agent at (404) 572-2447.

Respectfully submitted,

**/F. Brent Nix/**

F. Brent Nix  
Reg. No. 59,004

KING & SPALDING LLP  
1180 Peachtree Street, N.E.  
Atlanta, Georgia 30309-3521  
Telephone (404) 572-4600  
Facsimile (404) 572-5134